EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Task Force on Access to Data

Revision of the ENCePP Code of Conduct & Implementation Rules on access to data

Presented by:

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Chair of ENCePP Working Group 2 & Task Force on Access to Data

Review of the Code in 2011

2 step approach:

1) Task forces on access to data:

Review of issues in relation to the Code's provision on access to data.

➲ Concrete proposal to amend the Code or the implementation policy or for a data sharing policy

April/May 2011

2) Working Group 2:

General review of the Code based on log of issues and the outcome of the task force on access to data.

➲ Revision 2

June/July 2011

Task Force ‘Access to Data’

Participants:

Chair: H. Dolk

Thank you!

Morten Andersen
Miia Artama
Stella Blackburn
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Access to Data: TRANSPARENCY

Access to data may be requested by a third party for the purpose of

- *corroborating the study results in the interest of public health*
    - *Specific grounds/protocol*
- *to confirm compliance with the ENCePP Code of Conduct, e.g. completeness of the audit trail*
- *in the context of an audit by a competent authority.*

Researchers should as far as possible take an open and collaborative approach to data sharing

Access to Data – main amendments

Concern #1: **Means/How to provide access**, i.e. is it acceptable to provide access only locally?

Clarification:

☞ Different approaches acceptable, depending on situation:

- Written response
- Re-analysis by original researcher
- Collaboration
- Analysis by an independent third person
- On-site access
- Off-site access

☞ The chosen approach needs to be sufficient to address the issue raised by the applicant, and ensure full transparency (ENCePP SG as arbiter).

Access to Data – main amendments

Concern #2: Requirement to provide access to data might be contradictory to legal obligations for **data protection**, in particular for **sensitive data.**

Clarification:

- Definition of analytical data set introduced.
  - "the minimum set of data required to perform the statistical analyses leading to the results reported for the study and which, together with a complete audit trail describing the manipulation of raw data to obtain the analytic dataset, would be sufficient to allow a third party to repeat or corroborate the results."
- Clarification on need for data protection: It is acceptable to
  - modify the data set to remove personal identifiers.
  - only grant access to the data on-site and/or based on confidentiality or data sharing agreements.

Access to Data – main amendments

Concern #3: In studies using **secondary data** researchers might not have the right to provide access to the data to third parties due to **licence / governance rules** of the data provider.

Clarification:

- ☞ strive for most cost-effective approach (consider bilateral data sharing agreements and/or on-site access).
- ☞ Independent direct application for data in line with applicable licence and governance rules might be necessary.

Access to Data – other amendments

- Emphasis on preference of a collaborative approach towards data sharing
- Avoidance of language that implies that the re-analysis of data is necessarily more “correct” than the original analysis
- Additional requirements for qualification/interests of applicant for data sharing:
  - ENCePP study researcher may request
    - Proof of competency if necessary for proper handling and analysis of the data.
    - Declaration of interest in case of a (perceived) conflict of interest.
  - If such information is considered unsatisfactory, alternative options should be considered, e.g. analysis by an independent statistician.
- Compensation of costs incurred for providing access and/or additional analysis may be requested, but must be reasonable.

Access to Data – other amendments

- Requirement for additional research to be ENCePP compliant.
- All requests for access to be made public on the EncePP register of studies, including where access is refused with reasons for refusal (unless applicant withdraws)
- Audits: requirement to undertake all possible steps to provide for audits by competent authorities.
- Duration of access: At least up to a period in line with the requirements for the study archive in GPP (Guidelines for Good Pharmacoepidemiology Practices), i.e. 5 years after final report or first publication of study results, whichever comes later.
- Investigators should describe the procedure for access to the analytical data set in the study protocol, indicating the degree to which data can be shared and, if access is restricted, including a justification why access is limited.

Task Force - summary of changes

- Code of Conduct
  - Chapter 12 – core elements
  - Checklist (Annex 2)
  - Other chapters as necessary
  - Implementation Guidance to be included as Annex 4
- Implementation Guidance
  - Revised name 'Implementation Guidance for Sharing of ENCePP Study Data'
  - Substantial revision: $2^1/_2$ pages → 6 pages

Thank you!